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Velphoro (*sucroferric oxyhydroxide*)

An overview of Velphoro and why it is authorised in the EU

What is Velphoro and what is it used for?

Velphoro is a medicine used to control blood-phosphate levels in patients with long-term kidney disease:

- in adults who are on haemodialysis or peritoneal dialysis to remove waste products from the blood;
- in children aged from 2 years with severe kidney disease, including those on dialysis.

Velphoro should be used with a low-phosphate diet and other treatments such as calcium and vitamin D supplements which help to control bone disease linked to kidney failure and high phosphate levels.

The active substance in this medicine is sucroferric oxyhydroxide (also known as mixture of polynuclear iron(III)-oxyhydroxide, sucrose (sugar) and starches).

How is Velphoro used?

Velphoro is available as chewable tablets containing 500 mg of iron and as sachets of powder to take by mouth each containing 125 mg of iron. The medicine can only be obtained with a prescription.

The recommended starting dose of Velphoro in patients from 12 years of age is 3 chewable tablets a day, taken in divided doses at mealtimes. Phosphate levels in the blood should be monitored regularly and the dose is adjusted every 2 to 4 weeks, until the phosphate level remains within an acceptable range. The maximum dose is 6 tablets a day. The tablets must be chewed and not swallowed whole. Doses for children aged from 2 up to 12 years depend on their age and the medicine can be given as a powder, mixed with a small amount of soft food or water.

For more information about using Velphoro, see the package leaflet or contact your doctor or pharmacist.

How does Velphoro work?

In patients with severe kidney disease, the kidneys cannot remove phosphate from the blood. This leads to hyperphosphataemia (high blood phosphate levels), which, in the long term, can cause complications such as heart and bone disease.

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The active substance in Velphoro, sucroferric oxyhydroxide, is a phosphate binder. When patients take it with meals, the iron in Velphoro attaches to phosphate in the food, preventing phosphate being absorbed from the gut into the body and helping to keep down the phosphate levels in the blood.

What benefits of Velphoro have been shown in studies?

A main study involved 1,059 adults with hyperphosphataemia who were on dialysis for long-term kidney disease. Velphoro was as effective as another phosphate binder, sevelamer, in reducing patients' blood-phosphate levels and maintaining this effect. After 3 months of treatment, blood-phosphate levels fell on average by 0.7 mmol/litre with Velphoro compared with 0.8 mmol/litre with sevelamer, and after 6 months of treatment blood-phosphate levels were in the normal range (1.13 to 1.78 mmol/litre) for 53% of patients on Velphoro compared with 54% of patients on sevelamer.

Another study involved 85 adolescents and children from 2 years of age with chronic kidney disease and hyperphosphataemia. After up to 10 weeks of treatment, blood-phosphate levels fell on average by 0.12 mmol/litre with Velphoro. Blood-phosphate levels were in the normal range for 61% of patients on Velphoro.

What are the risks associated with Velphoro?

The most common side effects with Velphoro (which may affect more than 1 in 10 people) are diarrhoea, which may become less frequent with continued treatment, and discoloured faeces.

Velphoro must not be used in patients with iron accumulation disorders such as haemochromatosis (an inherited condition in which iron builds up gradually in the body and can cause damage to joints and organs).

For the full list of side effects and restrictions of Velphoro, see the package leaflet.

Why is Velphoro authorised in the EU?

The European Medicines Agency decided that Velphoro's benefits are greater than its risks and it can be authorised for use in the EU. The Agency concluded that Velphoro showed clear benefit in lowering phosphate levels. Although the reduction in phosphate levels in patients aged between 2 and 18 years was modest, the levels fell within the normal range for many patients after treatment with Velphoro. There were no major safety concerns and although side effects are slightly worse than with sevelamer, the overall safety profile was acceptable. The risk of excess iron build-up was considered low.

What measures are being taken to ensure the safe and effective use of Velphoro?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Velphoro have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Velphoro are continuously monitored. Side effects reported with Velphoro are carefully evaluated and any necessary action taken to protect patients.

Other information about Velphoro

Velphoro received a marketing authorisation valid throughout the EU on 26 August 2014.

Further information on Velphoro can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/velphoro.

This overview was last updated in 11-2020.